

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,	)	
	)	
v.	)	Criminal No. 17-295
	)	Judge Nora Barry Fischer
ANDRZEJ KAZIMIERZ ZIELKE,	)	

**MEMORANDUM ORDER**

**I. INTRODUCTION**

In this case, a federal grand jury returned a 121-count Superseding Indictment against Defendant Andrzej Kazimierz Zielke, a former medical doctor licensed in the Commonwealth of Pennsylvania, who previously operated Medical Frontiers, LLC, a pain management practice, with three locations in the Western District of Pennsylvania. (Docket No. 27 at ¶ 1). Specifically, Defendant is charged with 112 counts of unlawful dispensing and distributing schedule II controlled substances, in violation of [21 U.S.C. §§ 841\(a\)\(1\)](#) and [841\(b\)\(1\)\(C\)](#); one count of conspiracy to unlawfully distribute schedule II controlled substances, in violation of [21 U.S.C. § 846](#); four counts of health care fraud, in violation of [18 U.S.C. § 1347](#); and four counts of money laundering, in violation of [18 U.S.C. § 1957](#). (Docket No. 27). Presently before the Court is Defendant's motion to dismiss and the Government's opposition thereto. (Docket Nos. 53; 54). The Court held a motion hearing on November 12, 2019, the official transcript of which was filed on December 12, 2019. (Docket Nos. 61; 63). Per the Court's Order, Defendant filed a supplemental brief on January 13, 2020 and the Government filed a response on January 14, 2020. (Docket Nos. 64; 65). The matter is now fully briefed and ripe for disposition. After careful consideration of the parties' positions and for the following reasons, Defendant's Motion [53] is denied.

**II. LEGAL STANDARD**

The Federal Rules of Criminal Procedure require that an indictment be a plain, concise and definite written statement of the essential facts constituting the offense charged. [Fed. R. Crim. P. 7\(c\)\(1\)](#). An indictment is sufficient if it includes the elements of the offense intended to be charged, apprises the defendant of what he must be prepared to defend against at trial, and enables him to plead a former acquittal or conviction in the event of a subsequent prosecution. [United States v. Rawlins](#), 606 F.3d 73, 78-79 (3d Cir. 2010); [United States v. Vitillo](#), 490 F.3d 314, 321 (3d Cir. 2007). An indictment that fails to charge all elements of a crime must be dismissed. [United States v. Cochran](#), 17 F.3d 56, 57 (3d Cir. 1994).

[T]he scope of a district court's review at the Rule 12 stage is limited. "[A] pretrial motion to dismiss an indictment is not a permissible vehicle for addressing the sufficiency of the government's evidence." [United States v. DeLaurentis](#), 230 F.3d 659, 660 (3d Cir. 2000) (citations omitted). "The government is entitled to marshal and present its evidence at trial, and have its sufficiency tested by a motion for acquittal pursuant to [Federal Rule of Criminal Procedure 29](#)." *Id.* at 661. There is no criminal corollary to the civil summary judgment mechanism. *Id.* In evaluating a Rule 12 motion to dismiss, a district court must accept as true the factual allegations set forth in the indictment. [United States v. Sampson](#), 371 U.S. 75, 78-79, 83 S.Ct. 173, 9 L.Ed.2d 136 (1962); [United States v. Besmajian](#), 910 F.2d 1153, 1154 (3d Cir. 1990). "Evidentiary questions—such as credibility determinations and the weighing of proof—should not be determined at this stage." [Bergrin](#), 650 F.3d at 265 (internal marks and citation omitted). Thus, a district court's review of the facts set forth in the indictment is limited to determining whether, assuming all of those facts as true, a jury could find that the defendant committed the offense for which he was charged. [Panarella](#), 277 F.3d at 685; [DeLaurentis](#), 230 F.3d at 660.

[United States v. Huet](#), 665 F.3d 588, 595-96 (3d Cir. 2012).

### III. DISCUSSION

Defendant lodges three separate arguments in support of his motion to dismiss: (1) that the prohibited acts provision of the Controlled Substances Act ("CSA"), [21 U.S.C. § 841\(a\)\(1\)](#), is unconstitutionally vague as applied to him; (2) that [21 C.F.R. § 1306.04](#) allegedly expands the

scope of § 841(a)(1) and the Attorney General lacked the authority to issue such regulations pursuant to Subchapter 1, Part D of the CSA; and (3) that the Supreme Court's decision in *United States v. Moore*, 423 U.S. 122 (1975) allegedly authorizes only prosecutions of physicians who prescribe outside the scope of their DEA registration. (Docket Nos. 53; 64). The Government opposes each of Defendant's arguments and maintains that the Superseding Indictment sufficiently alleges the criminal charges against Defendant. (Docket Nos. 54; 65). The Court agrees with the Government's position and will deny the motion to dismiss for several reasons.

At the outset, all of Defendant's arguments fail to the extent that he relies upon matters outside the Superseding Indictment in support of dismissal as the governing legal standard precludes the Court from considering all of the following: the testimony at the hearing; the various exhibits presented by the parties; proffered expert testimony; and the defense's interpretation of the Government's expected trial evidence. See *Huet*, 665 F.3d at 595-96. Rather, the Court must focus on the allegations set forth in the Superseding Indictment, accept those facts as true, and determine whether the same, if proven, are sufficient that the jury could find that Defendant committed the crimes alleged. *Id.*

With that backdrop, the Court first turns to Defendant's position that the Superseding Indictment should be dismissed based upon his narrow interpretation of *Moore*, which essentially challenges the sufficiency of the pleading. (See Docket Nos. 53; 64). Defendant reasons that the grand jury's charges that he unlawfully distributed Schedule II controlled substances "outside the usual course of professional practice and not for a legitimate medical purpose" are deficient because they do not also allege that he prescribed them outside the scope of his DEA registration. (*Id.*). However, the law of the Third Circuit is clear that the grand jury was not even required to include allegations negating the exception to the § 841(a)(1) offenses that he, as a medical doctor,

illegally distributed narcotics outside the course of usual professional practice and not for a legitimate medical purpose. *See e.g., United States v. Polan*, 970 F.2d 1280, 1282 (3d Cir. 1992) (rejecting physician’s challenge to sufficiency of pleading because “the offense of illegal drug distribution by a physician contains three essential elements: the physician must (1) knowingly or intentionally (2) distribute (3) a controlled substance. The offense also includes an exception for drug distribution by a physician in the usual course of professional practice”); *United States v. Durante*, 612 F. App’x 129, 132 (3d Cir. 2015) (citing *Polan*, 970 F.2d at 1282) (“While an indictment must charge every essential element of an offense, it need not negate any exceptions to that offense. Similarly, the Superseding Indictment was not flawed for its failure to specify that Durante’s alleged drug distribution was illegal.”); *United States v. Berezna*, Crim. No. 3:18-CR-39, 2018 WL 1783171, at \*2 (M.D. Pa. Apr. 13, 2018) (“The Indictment is therefore sufficient because it alleges that Berezna prescribed the relevant medications outside the usual course of his professional practice, or for a purpose that was not medically legitimate.”). In short, the Government need not plead around the asserted defense that a physician allegedly cannot be liable for prescribing the types of controlled substances he is authorized to distribute under his DEA registration, a dubious proposition which is not supported by the prevailing caselaw. *See e.g., Moore*, 423 U.S. at 124 (“we hold that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice.”); *id.* at 131 (§ 822(b) “is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons.”).

At the same time, the Superseding Indictment is not a “bare bones” pleading merely parroting the relevant language from the pertinent statutes and regulations but contains numerous allegations supporting the 112 counts of unlawful distribution of Schedule II controlled substances

to multiple individuals on the dates specified in the Superseding Indictment. (Docket No. 27). To this end, paragraphs 1 through 8 of the Superseding Indictment detail various ways that Defendant's unlawful distribution of Schedule II controlled substances deviated from the usual professional practice and were not made for legitimate medical purposes. (*Id.* at ¶¶ 1-8). For example, he purportedly operated a pain management practice and required patients to pay cash to undergo "holistic" medical treatments such as ozone therapy, platelet rich plasmas injections, trigger point injections and vitamin supplements in order to receive prescriptions for controlled substances. (*Id.* at ¶¶ 1-5). He failed to adhere to basic standards and procedures of operating a medical practice, performing such procedures without using gloves and up-to-date testing kits and did not properly dispose of used needles, Sharps and medical waste. (*Id.* at ¶ 6). He sporadically ordered drug testing by third party laboratories but even when he obtained test results, he did not use them in his prescription practices. (*Id.* at ¶ 8). Defendant also changed prescription practices in 2016 after learning that he was being investigated by law enforcement by prescribing lower dosages of controlled substances to patients. (*Id.* at ¶ 7).

All told, the Court finds that the Superseding Indictment sufficiently alleges that Defendant committed 112 violations of [21 U.S.C. §§ 841\(a\)\(1\)](#) and (b)(1)(C). (Docket No. 27). Therefore, the Government "is entitled to marshal and present its evidence at trial, and have its sufficiency tested by a motion for acquittal pursuant to [Federal Rule of Criminal Procedure 29](#)." *Huet*, 665 F.3d at 595-96 (internal quotation omitted).

Defendant next claims that § 841(a)(1) of the CSA is void for vagueness as applied to him. As this Court held in *United States v. Taylor*, 232 F.Supp.3d 741, 754 (W.D. Pa. 2017), a criminal defendant bears a heavy burden to demonstrate that a criminal statute is void for vagueness. In this regard, a criminal statute may be deemed void for vagueness if the challenged statute:

(1) fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits; or (2) authorizes or even encourages arbitrary and discriminatory enforcement. The inquiry is undertaken on a case-by-case basis, and a reviewing court must determine whether the statute is vague as-applied to the affected party.

*United States v. Fullmer*, 584 F.3d 132, 152 (3d Cir. 2009) (internal citations and quotation marks omitted). “[T]he Supreme Court has held that scienter requirements in criminal statutes ‘alleviate vagueness concerns,’ because a *mens rea* element makes it less likely that a defendant will be convicted for an action that he or she committed by mistake.” *Id.* (citing *Gonzales v. Carhart*, 550 U.S. 124, 149, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007)).

Here, Defendant concedes that every Court of Appeals and District Court to consider the issue of whether the CSA is void for vagueness as applied to a medical professional has rejected the argument. (Docket No. 64 at 3, n.2 (citing cases)). The Government similarly points to persuasive authority denying such challenges. (Docket No. 54). The Court’s independent research did not uncover any cases in Defendant’s favor but located additional decisions against his position. *See e.g., United States v. Clarkson*, No. 5:18-CR-00026, 2020 WL 564039, at \*3 (S.D.W. Va. Feb. 4, 2020) (“the courts that have addressed the issue presented here have universally found that § 841(a)(1) is not unconstitutionally vague as applied to medical professionals.”); *United State v. Bynes*, No. CR418-153, 2019 WL 4635587, at \*3–4 (S.D. Ga. Aug. 29, 2019), *report and recommendation adopted sub nom. United States v. Bynes*, No. CR418-153, 2019 WL 4643858 (S.D. Ga. Sept. 23, 2019) (same). Overall, this Court is persuaded by the robust body of caselaw and likewise holds that the CSA is not void for vagueness as applied to Defendant given his status as a medical professional. *See Clarkson*, 2020 WL 564039, at \*3 (and cases cited therein).

Lastly, Defendant contends that the pertinent regulation, 21 C.F.R. § 1306.04, expands the

proscription of unlawful distribution of controlled substances in [21 U.S.C. § 841](#) and that the Attorney General lacked the authority to issue the regulations. (Docket Nos. 53; 64). Essentially, he maintains that it is up to Congress to proscribe criminal statutes and such task cannot be delegated to the Executive Branch. (*Id.*). Once again, Defendant has not provided the Court with any caselaw supporting these propositions or the relief sought that the instant Superseding Indictment be dismissed. (*Id.*). The Court also agrees with the Government that the cited regulation does not expand section 841. (Docket Nos. 54; 65). To the contrary, as noted above, the regulation sets forth an exception to the statutory bar for anyone to unlawfully distribute controlled substances akin to that set forth in related statutory provisions. *See e.g., Gonzales v. Oregon*, [546 U.S. 243, 244 \(2006\)](#) (“the underlying regulation here does little more than restate the terms of the statute itself,” i.e., 21 U.S.C. §§ 812(b), 829(c), and 802(21)); *United States v. Green*, [511 F.2d 1062, 1070 \(7th Cir. 1975\)](#) (“This interpretation does not expand the meaning of section 841(a), but rather seeks to define the exemption clause of that section.”); *Polan*, [970 F.2d at 1282](#) (“The offense also includes an exception for drug distribution by a physician in the usual course of professional practice.”). As with the statute, courts have also overruled objections that the regulation is void for vagueness. *United States v. Orta-Rosario*, [469 F. App’x 140, 143 \(4th Cir. 2012\)](#) (“Several other Circuits have explicitly ruled that the CSA and the regulations are not void for vagueness.”). Accordingly, Defendant’s motion to dismiss is denied on this basis as well.

#### IV. CONCLUSION

Based on the foregoing,

IT IS HEREBY ORDERED that Defendant’s Motion to Dismiss [53] is DENIED.

*s/Nora Barry Fischer*

Nora Barry Fischer, Senior U.S. District Judge

Dated: February 14, 2020

cc/ecf: All counsel of record.

Andrzej Kazimierz Zielke c/o Christopher Capozzi, Esq.